

REMARKS/ARGUMENTS

I. Status of the Claims

Claims 17-28 are currently pending. Upon entry of this amendment, claims 17, 21 and 23 are amended and claims 18-20, 22 and 24-28 canceled without prejudice or disclaimer. Applicants reserve the right to reintroduce the unamended or canceled claims in this or another application. Claims 17, 21 and 23 are thus pending following entry of this amendment. Amended claim 17 combines elements of claims 17, 19, and 22.

II. Claim Objection

The objection to the typographical error in claim 18 is rendered moot because this claim is canceled in this amendment.

III. Priority

The Examiner acknowledges receipt of the certified copy of the priority document mailed May 14, 2004. The Examiner, however, states that a certified translation of the priority document is required to perfect the priority claim because the certified document is in German.

MPEP 201.14 lists only two requirements for a claim to foreign priority, stating that the applicant must: 1) file a priority claim, and 2) submit a certified copy of the original foreign application. Since these two conditions have been satisfied, Applicants submit that a translation is not required under the current circumstances. The limited instances when a translation is required (see, e.g., 37 CFR 1.55 (a)(4) and MPEP 201.014(a)) do not seem to apply here. If the Examiner still believes a translation is required, Applicants request clarification of the basis for the requirement.

IV. Objections to the Specification

The sections of the specification noted by the Examiner as containing typographical or grammatical errors have been corrected as requested.

V. Rejection of Claims under 35 U.S.C. 112, Second Paragraph

The rejection of claim 18 as allegedly being indefinite is rendered moot by cancellation of this claim.

VI. Double Patenting

Claims 17-19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 23 of U.S. Patent No. 6,228,613. Applicants note in response that independent claim 17 has been amended to read:

A pharmaceutical preparation comprising a factor VIII/von Willebrand Factor complex (factor VIII/vWF-complex) containing high-molecular weight vWF multimers having a specific vWF activity of at least 66 U/mg protein and a specific factor VIII activity of at least 500 U/mg protein.

The vWF activity level in current claim 17 is substantially higher than that listed in claim 23; nor does claim 23 state the level of purity of factor VIII as in amended claim 17. Applicants submit that claim 17 as amended is not obvious over claim 23 of U.S. Patent No. 6,228,613. Reconsideration is requested.

VIII. Claim Rejections under 35 U.S.C. § 102 and § 103

A. Claim 17

Claim 17 stands rejected as obvious over EP 705,846 to Fischer et al. (corresponds to U.S. 5,869,617) ("Fischer"). Fischer is said to discuss combining factor VIII with vWF and methods for separating high molecular weight vWF from low molecular weight vWF. The Office Action points to a section of the specification for support of the proposition that it was known in the art that factor VIII complexed with high molecular weight vWF was preferred for treating bleeding disorders. It is thus concluded that it would have been obvious to combine the high molecular weight vWF discussed in Fischer with factor VIII for use in treating blood disorders.

In response, Applicants submit that Fischer does not teach or suggest a pharmaceutical preparation comprising a factor VIII/vWF complex that has *either* a specific vWF activity of at least 66 U/mg protein or a specific factor VIII activity of at least 500 U/mg protein. Claim 17 is thus patentable over Fischer for at least this reason. None of the other cited references remedy this deficiency in Fischer.

B. Claims 24-26

Claims 24-26 are rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, rejected under 35 U.S.C. § 103(a) as obvious over EP 600480 to Arrighi et al. ("Arrighi"). These claims are also alleged to be anticipated by or rendered obvious over Burnouf et al. (Protein Expression and Purification, vol. 5, pages 138-143, 1994) ("Burnouf"). Although not agreeing or acquiescing to the basis for these rejections, claims 24-26 have been cancelled to expedite prosecution of important subject matter. Cancellation of these claims renders this rejection moot.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 303-571-4000.

Respectfully submitted,



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